

IN RE APPLICATION OF: §  
J. Easterling §

SERIAL NO. 10/044,288 §

EXAMINER: HUI, SAN MING R.

FILED: 10/24/2001 §

GROUP ART UNIT: 1617 §

TITLE: Composition and Method..

MAIL STOP AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF WILLIAM P. FITCH III, MD UNDER 37 C.F.R. 1.132**

My name is William P. Fitch III, MD. I am a board certified urologist and practiced in the field of urology for twenty eight years. I received my primary medical training at Tulane Medical School and completed a residency in urology at the University of Texas Health Science Center in San Antonio, Texas. .

My professional affiliations and activities are reflected in my curriculum vitae which is attached to this declaration.

As is typical for most urologists according to my experience, my practice from its inception has involved the treatment of men with Peyronie's disease. Urology is the field in which Peyronie's disease is treated, researched, and featured in peer reviewed journals. I am familiar with, and have been involved directly with delivery of all conventional treatments for Peyronie's disease. I am presently treating a substantial number of Peyronie's disease sufferers.

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Until the introduction of topical calcium channel blocker preparations by Jerry Easterling, my practice in treating Peyronie's disease sufferers conformed to conventional treatment regimens. In cases of short-term Peyronie's disease symptoms, I typically recommended a wait-and-see approach in view of the capacity for certain Peyronie's disease symptoms to reverse spontaneously, and in further view of the expense, risk of side effects, frequent lack of efficacy, and (in some cases) excruciating pain involved in conventional treatments.

In cases of prolonged Peyronie's disease symptoms, without any indication of spontaneous healing, my practice evolved into suggesting surgical intervention, but only after trying (with very limited success) alternative treatment regimens which included intralesional injections of calcium channel blockers, the use of topical vitamin E, and a variety of other treatments which have been suggested in the urology field. Prior to Jerry Easterling's invention, surgical removal of the plaques of Peyronie's disease was the only consistently reliable treatment regimen in reversing Peyronie's disease symptoms. Such surgery involved not only the usual risks associated with any surgical procedure, as well as the cost, but in this particular case involved risks of post operative impotence and of diminished penile length and girth. Further still, surgical removal of Peyronie's disease plaques in no way insures that the condition will not return at a later time.

Upon initially hearing of Mr. Easterling's suggestion of a treatment for Peyronie's disease relying solely on a topical medication, I was extremely skeptical of any efficacy.

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In view of the dismal efficacy of prior treatment regimens which involved direct intervention with the plaques of Peyronie's disease, I found it very difficult to believe that any topical preparation could have any material therapeutic effect in the treatment of Peyronie's disease. More specifically relating to Mr. Easterling's proposed topical verapamil preparation, I could not readily accept that a substance with limited efficacy when injected directly into the plaques of Peyronie's disease could possibly be effective when merely applied topically, even when combined with a vehicle for transdermal delivery.

After accepting the fact that there would be no undue risk to my Peyronie's disease patients, but with limited expectation of success, I prescribed Mr. Easterling's topical verapamil preparation to some of my longer suffering patients. To my astonishment, the topical verapamil achieved significant reversals of Peyronie's disease symptoms, even in cases of extremely prolonged and treatment resistance Peyronie's disease symptoms. Of 196 patients with penile curvature and treated with the topical verapamil preparation, 140 (71.4 percent) exhibited decreased curvature. Of 200 patients with measurable plaque, 173 (86.5 percent) had measurable improvement. Of 89 patients with erectile dysfunction related, at least in part, to Peyronie's disease, 49 (55.1 percent) experienced improvement in erectile rigidity. Of 70 patients with reported pain associated with Peyronie's disease 100 percent had complete relief of pain. There was only a 1.4 percent incidence of contact dermatitis, but two of three such patients

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improved with topical corticosteroids.

The rate of reversals of Peyronie's disease symptoms enjoyed by my patient population far exceeded the rate of spontaneous reversals seen in prior experience, as well as that of prior non-surgical treatment regimens.

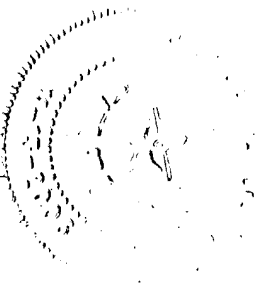
I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

William P. Fitch III

William P. Fitch III, MD

8/20/04

Date



SUBSCRIBED AND SWORN BEFORE ME  
THIS 20 DAY OF August 2004  
Janice Konec  
NOTARY PUBLIC

DR. WILLIAM FITCH CURRICULUM VITAE

NAME: William Pilcher Fitch, III, M.D.

ADDRESS: Private Practice  
Urology Consultants, P.A.  
8038 Wurzbach, Suite 430  
San Antonio, Texas 78229  
210-616-0410

AFFILIATION DATE: Private Practice of Urology  
July 1, 1976 to Present

DATE OF BIRTH: May 6, 1943

UNDERGRADUATE SCHOOL: University of Texas  
Austin, Texas - B.A. 1964

MEDICAL SCHOOL: Tulane University Medical School  
New Orleans, Louisiana - M.D. 1968

INTERNSHIP: The University of Texas Health  
Science Center at San Antonio  
Affiliated Hospitals 1968-1969

RESIDENCY: The University of Texas Health  
Science Center at San Antonio  
Affiliated Hospitals 1969-1970  
1972-1976

MILITARY: United States Air Force 1970-1972

LICENSURE: Texas D5728  
Louisiana R#E14130, L#010798

SOCIETIES &  
MEMBERSHIPS: American Cancer Society Board of  
Directors 1977-1980  
American College of Surgeons  
American Medical Association  
American Urologic Association  
Bexar County Medical Society  
International Society for Impotence  
Research, Chairman, Finance Committee  
1994-1996  
Planned Parenthood of San Antonio,  
Board of Clinical Advisors -  
1976-1990  
San Antonio Chapter of Impotents  
Anonymous - Founder  
San Antonio Chapter of Impotents  
Anonymous - Medical Director  
San Antonio Surgical Society

SOCIETIES &  
MEMBERSHIP: (cont'd)

San Antonio Urologic Society  
Secretary - 1977-1978  
San Antonio Urologic Society  
President - 1978-1979  
Society for the Study of Impotence,  
Audit Committee, 1995-1996  
Guidelines Committee, 1998-1999  
Southern Medical Association  
Texas Medical Association  
Texas Medical Foundation

BOARD CERTIFIED:

American Board of Urology  
February 8, 1978

CIVIC ACTIVITIES:

Leadership San Antonio, 1978-1979  
Board of Directors, San Antonio, Texas  
Exes, 1973-1977  
Executive Council, Texas Exes, 1976-1977  
and 1980-1983  
Board of Trustees, Alamo Heights  
Independent School District,  
1980-1986; 1992-1998  
President, Alamo Heights Independent  
School District, 1982-1983  
Boards and Commissions Task Force, San  
Antonio Greater Chamber of Commerce  
Action Council Member, National  
Federation of Independent Business  
Chamber of Commerce of the United States  
of America

APPOINTMENTS:

Instructor, Department of Surgery  
Division of Urology  
The University of Texas Health Science  
Center at San Antonio 1/1976 - 6/1976

Clinical Instructor  
Department of Surgery  
Division of Urology  
The University of Texas Health Science  
Center at San Antonio 6/1976 - 1986

Clinical Assistant Professor  
Department of Surgery  
Division of Urology  
The University of Texas Health Science  
Center at San Antonio 6/1976 - 1986

Clinical Assistant Professor  
Department of Surgery  
Division of Urology  
The University of Texas Health Science  
Center at San Antonio 1987-1988

Clinical Associate Professor  
Department of Surgery  
Division of Urology  
The University of Texas Health Science  
Center at San Antonio 1988 - Present

APPOINTMENTS: (cont'd)

Chief, Department of Urology  
St. Luke's Lutheran Hospital  
San Antonio, Texas 1979-1980

Chief, Department of Urology  
San Antonio Community Hospital  
San Antonio, Texas 1980-1981

Vice Chief of Staff  
San Antonio Community Hospital  
San Antonio, Texas 1982

Chief of Staff Elect  
San Antonio Community Hospital  
San Antonio, Texas 1983

Chief of Staff  
Humana Hospital San Antonio  
San Antonio, Texas 1984

Chief, Urological Residency Training  
Program  
Humana Hospital San Antonio  
San Antonio, Texas 1984

AWARDS: Listed in Best Doctors in America, 1994-Present.

BIBLIOGRAPHY:

1. Radwin, H.M., Fitch, W.P. and Robinson, J.R.: A Unified Concept of Renal Trauma. J. Urol. 116:20-22, 1976.
2. Radwin, H.M., Fitch, W.P. and Robinson, J.R.: Metastatic Carcinoma of the Ureter. Arch of Surg. III:874-876, 1976.
3. Fitch, W.P.: Reduction Cavernosoplasty. Videourology, Vol. 3, Program 3, 1990.
4. Roddy, T. and Fitch, W.P.: Erosion of Inflatable Penile Prosthesis Reservoir into the Bladder. J. Urol. 136:1080, 1986.
5. Rosenthal, S.H. and Fitch, W.P.: The Antiherpetic Effect of Phenelzine (letter). J. Clin. Psychopharmacology. 7(2):119, 1987.
6. Kaufman, J.M., Borgus, F.D., Fitch, W.P., Giller, R.A., Gruber, M.B., Hubbard, J.G., McKay, D.L., Tuttle, J.P. and Witten, F.R.: Evaluation of Erectile Dysfunction by Dynamic Infusion Cavernosometry and Cavernosography (DICC). Urology 41:445-451, 1993.
7. Cookson, M.S., Phillips, D.L., Huff, M.E. and Fitch, W.P.: Analysis of Microsurgical Penile Revascularization Results by Etiology of Impotence. J. Urol. 149:1308-1312, 1993.
8. Goldstein, I., Bertero, E.B., Kaufman, J.M., Witten, F.R., Hubbard, J.G., Fitch, W.P., Geller, R.A., McKay, D.L., Krane, R.J., Borges, F.D., Babayan, R.K., Tuttle, J., Gruber, M., Harik, V., and Levenson, S.: Early Experience with the First Pre-Connected 3-Piece Inflatable Penile Prosthesis: The Mentor Alpha-1. J. Urol. 1993.

9. Kaufman, J.M., Hatzichrostow, D.G., Mulhall, J.P., Fitch, W.P., and Goldstein, I.: Impotence and Chronic Renal Failure: A Study of the Hemodynamic Pathophysiology. J. Urol. 1994.
10. McConnell, J., Bruskewitz, R., Walsh, P. Andriole, G., Lieber, M., Holtgrewe, L., Albertsen, P., Roehrborn, C., Nickel, J., Wang, D., Taylor, A., Waldstreicher, J. (For the Finasteride Long-Term Efficacy and Safety Study Group): The Effect of Finasteride on the Risk of Acute Urinary Retention and the Need for Surgical Treatment Among Men with Benign Prostatic Hyperplasia. New England J. of Medicine. 338:557-563, 1998.
11. Roehrborn, C., McConnell, J., Lieber, M., Kaplan, S., Geller, J., Malek, G., Castellanos, R., Coffield, S., Saltzman, B., Resnick, M., Cook, T., Waldstreicher, J., (For the PLESS Study Group): Serum Prostate Specific Antigen Concentration is a Powerful Predictor of Acute Urinary Retention and Need for Surgery in Men with Clinical Benign Prostatic Hyperplasia. Urology 53:696-700, 1999.
12. Roehrborn, C.G., McConnell, J., Bonilla, J., Rosenblatt, S., Hudson, P.B., Malek, G.H., Schellhammer, P.F., Bruskewitz, R., Matsumoto, A.M., Harrison, L.H., Fuselier, H.A., Walsh, P., Roy, J., Andriole, G., Resnick, M., Waldstreicher, J., (For the PLESS Group): Serum Prostate Specific Antigen is a Strong Predictor of Future Prostate Growth in Men with Benign Prostatic Hyperplasia. J. Urology 163:13-20, 2000.

#### ABSTRACTS PUBLISHED:

1. Goldstein, I., Bertero, E.B., Kaufman, J.M., W. Hen, F.R., Hubbard, J.G., Fitch, W.P., Geller, R.A., McKay, D.L., Krane, R.J., Borges, F.D., Babayan, R.K., Tuttle, J., Gruber, M., Harik, V., Levenson, S.: Multi-Institutional Surgical Outcome Study Utilizing the Mentor Alpha-1 Inflatable Penile Prosthesis. International J. of Impotence Research. 4:A128, 1992.
2. Fitch, W.P., Kaufman, J.M., Borges, F.D., Tuttle, J.P., Witten, F.R., Hubbard, J.G., Gruber, M.B., McKay, D.L., Geller, R.A., Kettlehut, M.: Analysis of Microsurgical Penile Revascularization in Multiple Institutions Using Similar Preoperative Selection Criteria. International J. of Impotence Research. 4:R191, 1992.
3. Fitch, W.P., Borges, F.D., Kaufman, J.M., Tuttle, J.P., Witten, F.R., Hubbard, J.G., McKay, D.L., Gruber, M., Geller, R.A., Kettlehut, M.: Analysis of Corporal-Veno-Occlusive Surgery in Multiple Institutions Using Similar Preoperative Selection Criteria. International J. of Impotence Research. 4:P204, 1992.
4. Fitch, W.P., Kaufman, J.M., Borges, F.D., Tuttle, J.P., Witten, F.R., Hubbard, J.G., Gruber, M.B., McKay, D.L., Kettlehut, M., Heine, G.: Effect of Risk Factors Upon Microsurgical Penile Revascularization Postoperative Results. International J. of Impotence Research. 6:D26, 1994.



5. Kaufman, J.M., Kaufman, J.L., Fitch, W.P.: Deep Dorsal Vein Arterialization in Arteriogenic Impotence: Use of Dorsal Artery as Neoarterial Source.  
International J. of Impotence Research. 6:D27, 1994.
6. Fitch, W.P.: Patient Acceptance of Vacuum Erection Device and Intracavernosal Injection in the Treatment of Impotence.  
International J. of Impotence Research. 6:D177, 1994.
7. Kaufman, J., Goldstein, I., Tuttle, J., Castellanos, R., Fitch, W., Gittelman, M., Albrecht, D., and the Alprostadil Alfadex Study Group: Placebo-Controlled Double-Blind Study of Alprostadil Alfadex for Self-Injection Therapy at Home.  
International J. of Impotence Research. 8:142, 1996.
8. Fitch, W.P.: Seventeen Year Experience Using Inflatable Penile Prosthesis.  
International J. of Impotence Research. 8:157, 1996.
9. Fitch, W.P.: Topical Verapamil for the Treatment of Peyronie's Disease.  
International J. of Impotence Research. 11:S86, 1999.
10. Roehrborn, C., Boyle, P., Bergner, D., Gray, T., G. Hleman, M.D., Shown, T., Melman, A., Bracken, B., de Vere White, R., Taylor, A., Wang, D., Waldstreicher, J., (For the PLESS Study Group): Serum Prostate-Specific Antigen and Prostate Volume Predict Long-Term Changes in Symptoms and Flow Rate: Results of a Four-Year, Randomized Trial Comparing Finasteride Versus Placebo. *Urology* 54:662-669, 1999.
11. Bruskewitz, R., Girman, C., Fowler, J., Rigby, O., Sullivan, M., Bracken, R., Fusilier, H., Kozlowski, D., Kantor, S., Johnson, E., Wang, D., Waldstreicher (For the PLESS Group): Effect of Finasteride on the Degree that Symptoms Bother Men and Other Health-Related Aspects Associated with Benign Prostatic Hyperplasia. *Urology* 54:670-678, 1999.

#### POSTER PRESENTATIONS:

The International Society for Impotence Research, Boston, Massachusetts  
10/06/88 - 10/09/88 "Common Penile Artery Arising From Femoral Artery".

IV World Meeting on Impotence, VII Symposium on Corpus Cavernosum  
Revascularization, Rio de Janeiro, Brazil  
09/02/90 - 09/06/90

"Result of Penile Revascularization Using Similar Criteria in Multiple Treatment Centers".

"Surgical Treatment of Venous-Occlusive Insufficiency Using Similar Preoperative Criteria in Multiple Treatment Centers".

"Rescuing the Failed Papaverine/Phentolamine Erection: A Proposed Synergistic Action of Papaverine, Phentolamine and Prostaglandin E<sub>1</sub>".

"Evaluation of Erection Dysfunction Using Dynamic Infusion Cavernosometry and Cavernosography".

5th World Meeting on Impotence, Milan, Italy  
09/17/92 "Analysis of Microsurgical Penile Revascularization in Multiple Institutions Using Similar Preoperative Selection Criteria".

5th World Meeting on Impotence, Milan, Italy  
09/17/92 "Venous Surgery - Miscellaneous".

Annual Meeting, American Urological Association, San Antonio, Texas  
05/17/93 "Impotence: Diagnosis and Treatment".

23rd Congress-Societe International D'Urologie, Singapore  
09/13/94 "Effect of Risk Factors Upon Microsurgical Penile Revascularization Post-Operative Results".  
09/15/94 "Patient Acceptance of Vacuum Erection Device and Intracavernosal Injection in the Treatment of Impotence".

AUA, Las Vegas, Nevada  
04/25/95 "Effect of Risk Factors upon Microsurgical Penile Revascularization: Postoperative Results".

VII World Meeting on Impotence, San Francisco, California  
11/05/96 "Placebo-Controlled Double-Blind Study of Alprostadil Alfadex for Self-Injection Therapy at Home".

American Urological Association, San Diego, California  
05/30/98 "BPH: Medical and Hormonal Therapy II".

Annual Meeting, American Urological Association, San Diego, California  
06/03/98 "Long-Term Experience with Finasteride in Treatment of BPH: Sexual Adverse Experiences are Similar Between Treated and Placebo Groups after the First Year of Therapy".

American Urological Association, Atlanta, Georgia  
05/02/99 "Infection Prophylaxis for Revision of Penile Prosthetic Devices"

9th World Meeting on Impotence Research, Perth Western Australia.  
11/27/00 "Topical Verapamil and trifluoperazine for Peyronie's Disease".  
11/28/00 "Infection Prophylaxis for Revision of Penile Prosthetic Devices".

Sexual Medicine Society, 4th Annual Fall Meeting, Charleston, South Carolina  
12/08/01 "Topical Verapamil, Trifluoperazine, and Magnesium Sulfate for Peyronie's Disease".

American Urological Association, Orlando, Florida  
05/27/02 "Topical Verapamil, Trifluoperazine, and Magnesium Sulfate for Peyronie's Disease".

#### AWAITING PUBLICATION:

Yang, X., Leckshell, K., Short, K., Gottesman, J., Peterson, L., Bannow, J., Schellhammer, P., Rous, S., Fitch, W., Hodge, G., Parra, R., Waldstreicher, J., Epstein, J. (For the PLESS Study Group): Does Long-Term Finasteride (Proscar) Affect the Histology of Benign Prostate Tissue and Prostate Cancer or Needle Biopsy?

Rendell, M., Ratfer, J., Wicker, P., Smith, M., (For the Sildenafil Diabetes Study Group): Sildenafil for the Treatment of Erectile Dysfunction in Men with Diabetes: A Randomized Controlled Trial.

Roehrborn, C.G., Boyle, P., Gould, A.L., and Waldstreicher, J.: Serum Prostate-Specific Antigen as a Predictor of Prostate Volume in Men with Benign Prostatic Hyperplasia. Urology 53:581-589, 1999.

Roehrborn, C. Bruskewitz, R., Nickel, J., Glickman, S., Cox, C., Anderson, R., Kandzari, S., Herlihy, R., Kornitzer, G., Brown, B., Holtgrewe, L., Taylor A., Wang, D., Waldstreicher, J., (For the PLESS Study Group): Urinary Retention in Patients with BPH Treated with Finasteride or Placebo Over Four Years: Characterization of Patients and Ultimate Outcomes.

Kaplan, S., Garvin, D., Gilhooly, D., Koppel, M., Labasky, R., Milsten, R., Reddy, P., Rosenberg, S., Sussman, D., Whit, C., Lee, M., Pappas, F., Waldstreicher, J. (For the PLESS Group): The Impact of Baseline Symptom Severity on Future Risk of BPH-Related Outcomes and Long-Term Response to Finasteride.

Bruskewitz, R., Girman, C.J., Fowler, J., Rigby, O.F., Sullivan, M., Bracken, R.B., Fusilier, H.A., Kozlowski, D., Kantor, S.D., Johnson, E.L., Wang, D.Z., Waldstreicher, J. (For the PLESS Study Group): Effect of Finasteride on BOTHER and Other Health-Related Quality of Life Aspects Associated with Benign Prostatic Hyperplasia.

#### ADVISORY POSITIONS:

Medical Advisory Board, Urology Nurse Journal.

Board of Editorial Advisors, Sex over Forty.

Medical Quality Assessment Advisory Committee, Prime Medical Services, Inc.

#### RESEARCH EXPERIENCE:

Investigator in a trial showing the effect of diabetes mellitus on cholinergic nerves in human corpus cavernosum.  
Investigator in a trial of penile vascular reconstruction.  
Investigator in a trial showing incidence of vascular impotence following renal transplantation.  
Investigator in a trial using inflatable penile prosthesis.  
Investigator in a trial for human renal allograft refection: Effector mechanism.

Investigator in a randomized prospective clinical trial of third-party blood transfusion vs. cyclosporine therapy in living related renal transplant recipients.

Investigator in a clinical trial showing the effect of phenelzine on genital herpes.

Investigator in a clinical trial of conventional immunosuppressant after deliberate third-party transfusion vs. cyclosporine in living related renal transplant recipients.

Investigator in a clinical trial of the use of verapamil to reduce cyclosporin A.

Investigator in a trial showing the effect of fish oil in an attainable dietary amount on cyclosporine toxicity in the rat.

Investigator in a trial showing the effect of diethylstilbestrol in relation to corporeal cavernosal fibrosis.

Investigator in a clinical trial showing the comparison of the drop-out rate between users of the vacuum constriction device (VCD) and the pharmacologic program (PEP) in the treatment of male sexual dysfunction.

Investigator in a clinical trial showing the use of post-transplant allograft growth as an indicator of renal function of kidneys from pediatric donors.

Investigator in a trial for development of criteria to redefine the profile of the "High Risk" renal transplant recipient.

Investigator in a trial for the development of criteria to redefine the profile of the "High Risk" donor.

Investigator in a clinical trial of a powder formulation for the treatment of erectile dysfunction.

Investigator in a clinical trial for an oral medication in the treatment of symptomatic benign prostatic hyperplasia.

Investigator in a clinical trial for an oral antibiotic in the treatment of pyelonephritis and complicated urinary tract infections.

Investigator in clinical trials of medications in the treatment of benign prostatic hyperplasia.

Investigator in clinical trials of medications in the treatment of erectile dysfunction.

Investigator in clinical trials of medications in the treatment of erectile disorder.

Investigator in a clinical trial showing the acceptability of Testoderm Testosterone Transdermal Systems.

Investigator in a brief pilot study to determine the use of an oral medication in the treatment of erectile dysfunction.

Investigator in a clinical trial of an oral antibiotic in the treatment of prostatitis.

Investigator in several long-term clinical trials for oral medications for erectile dysfunction.

Investigator in clinical trials for 2nd line therapy in prostate cancer.

Sub-investigator in a clinical trial for medications for bladder cancer.

Sub-investigator in clinical trials for overactive bladder.

Investigator in pilot study for treatment of benign prostatic hyperplasia.

Investigator in pilot study for the use of verapamil to reduce the size of penile plaques due to Peyronie's disease.